IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NORTHWESTERN UNIVERSITY,	)	
	)	
Plaintiff,	)	C.A. No. 24-1151-RGA
	)	
v.	)	**Jury Trial Demanded**
	)	
MODERNA, INC., MODERNATX, INC., AND MODERNA US, INC.,	)	
	)	
	)	
Defendants.	)	

PLAINTIFF NORTHWESTERN UNIVERSITY'S ANSWERING BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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January 23, 2025

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I. SUMMARY OF THE ARGUMENT

Patent litigation can be costly and protracted. Northwestern University attempted to avoid unnecessary expense in an October 2023 letter by proposing a license to the Defendants ("Moderna"). In that letter, Northwestern notified Moderna that its products used a lipid nanoparticle platform that practiced Northwestern's patents. Moderna did not agree to a license, and it is now doing its best to make this litigation onerous for Northwestern. Rather than address Northwestern's claims on the merits, Moderna uses its motion to raise a flurry of meritless issues.

Of Moderna's seven arguments, five only work if the Court agrees with Moderna's inaccurate descriptions of the applicable law. Moderna misstates (1) the standard for pleading "make" and "use" direct infringement, (2) the standard for pleading pre-suit knowledge of indirect infringement, (3-4) the standard for pleading no substantial non-infringing use (a misstatement Moderna commits for both the Section 271(c) and 271(f) claims), and (5) the standard for pleading willfulness. Moderna fares no better with its last two arguments. Its sixth argument is a quixotic attempt to claim that Northwestern did not allege "physisorbed" claim limitations that the complaint plainly addresses. Finally, Moderna invites the Court to invalidate the '686 patent through a Section 101 argument in which Moderna never identifies the supposedly invalidating natural phenomenon.

Northwestern asks that the Court decline Moderna's invitation to delay this litigation with its meritless arguments to dismiss. The Court should deny the motion: Northwestern adequately pled its complaint.

II. COUNTERSTATEMENT OF THE FACTS

A. Moderna needed the technological solutions that Northwestern pioneered

As the COVID-19 virus spread across the world, researchers scrambled to create a vaccine to protect against the disease. D.I. 1 (Complaint) at ¶ 29. Using genetic code in the form of mRNA, Moderna had developed a way to tell the body how to build immunity to the virus without ever experiencing an infection. *Id.* ¶¶ 32-34. But they needed a way to deliver the code into the cell. *Id.* ¶¶ 47-48. Moderna previously recognized it was "too underfunded and small to create its own delivery system." *Id.* (citation omitted). They would need the research and development of others. *Id.*

For years, researchers had explored ways of solving the challenges associated with delivering nucleic acids into cells, which includes endosomal sequestration, cell mistargeting, and toxic reactions. *Id.* ¶¶ 42-48. Several Northwestern researchers, including Dr. Chad Mirkin and Dr. Shad Thaxton, achieved a breakthrough in the lipid nanoparticle technology needed to deliver genetic code into a cell. *Id.* ¶ 54. Dr. Chad Mirkin is a global leader in biological nanotechnologies, whose work received hundreds of awards and patents. *Id.* ¶ 50. Dr. Shad Thaxton began his work in Dr. Mirkin's lab, and he quickly garnered national acclaim, including a recognition from President Barack Obama for his early career achievements. *Id.* ¶ 53. Their solution featured synthetic lipid nanoparticles inspired by lipoproteins, naturally occurring particles that transfer molecules in and out of cells. *See id.* ¶¶ 57-61.

B. The inventors claimed their breakthroughs in the Asserted Patents

Dr. Mirkin, Dr. Thaxton, and the other inventors disclosed their inventive nanoparticles in the Asserted Patents, claiming nanoparticles with a core, shell, particular lipids, and apolipoproteins. *See id.* ¶¶ 63-81. The inventors recognized that their inventive nanoparticles were "important in order to fully realize the potential of nucleic acid-based therapies." *Id.* ¶ 76

(quoting D.I. 1-2, Ex. J ('026 patent) at 6:3-6). Like lipoproteins, the inventive nanoparticles could "successfully navigate the bio-nano interface for targeted and chemically triggered release of regulatory nucleic acids." '026 patent, 6:3-6; *see also* D.I. 1-2, Ex. K ('686 patent) at 14:59-66. The inventors also recognized that a party could design a nanoparticle with properties that facilitated apolipoprotein binding. D.I. 1 at ¶¶ 78-79. As a result, the patents contemplated that the claimed particles could form after administration to a patient: "in some cases a structure described herein includes a core and a shell which is administered in vivo or in vitro, and the structure has a greater therapeutic effect after sequestering one or more components (e.g., an apolipoprotein) from a subject or biological sample." '026 patent, 23:51-56; '686 patent, 15:9-14. "[T]he structure may use natural components from the subject or biological sample to increase efficacy of the structure after it has been administered." '026 patent, 23:56-59; '686 patent, 15:14-16. And the Asserted Patents taught how to create structures that would allow for these favorable interactions. *See, e.g.*, '026 patent, 16:34-38; '686 patent, 7:54-58. Years later, Moderna would recognize the inventiveness and usefulness of the inventors' contributions by citing to Northwestern's patents. D.I. 1 at ¶¶ 82-84. They would also employ these teachings in the nanoparticles that delivered its mRNA.

C. Moderna uses the technology claimed in the Asserted Patents

Moderna practices the technology of the Asserted Patents through the lipid nanoparticle platform used in its Spikevax (COVID-19) and mRESVIA (RSV) vaccines. *Id.* ¶¶ 87, 117. The Accused Products contain a core and a lipid shell, and Moderna designs them to ensure that they bind with a patient's apolipoproteins. *See id.* ¶¶ 127, 141, 155.

On October 13, 2023, Northwestern notified Moderna that its products practiced the technology of the Asserted Patents. *See* D.I. 14-1, Moderna Ex. 1 (Northwestern letter to Moderna (Oct. 13, 2023)). Northwestern identified each of the Asserted Patents in the letter. *Id.*

Northwestern identified how the "LNP delivery system" practiced the technology. *Id.* at 2. Northwestern asked Moderna to enter into a "licensing arrangement" to authorize its use of this technology. *Id.* Moderna refused. D.I. 1 at ¶ 14.

III. LEGAL STANDARD

Rule 8 requires a plaintiff only to provide a complaint with "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "The Federal Rules of Civil Procedure do not require a plaintiff to plead facts establishing that each element of an asserted claim is met." *Bot M8 LLC v. Sony Corp. of Am.*, 4 F.4th 1342, 1352 (Fed. Cir. 2021) (quoting *In re Bill of Lading Transmission & Processing Sys. Pat. Litig.*, 681 F.3d 1323, 1335 (Fed. Cir. 2012)). The plaintiff must plead enough to "give the alleged infringer fair notice of infringement." *Id.* Rule 12(b)(6) allows a defendant to move to dismiss a complaint only if it lacks enough factual matter to state a facially plausible claim to relief, after taking all factual allegations as true. *Bench Walk Lighting LLC v. LG Innotek Co.*, No. 20-cv-51-RGA, 2022 WL 606287, at *1 (D. Del. Jan. 4, 2022) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

IV. ARGUMENT

A. Northwestern plausibly alleged that Moderna directly infringes through Accused Products specifically designed to practice the Asserted Patents

Northwestern served Moderna with a complaint alleging direct infringement of the Asserted Patents. The complaint thoroughly pled how Moderna "makes" and "uses" the claimed nanostructures by designing particles that form into the infringing structures upon administration—just as the patent specification contemplated could occur. But Moderna did not engage with the allegations or any law associated with direct infringement. Instead, Moderna offered the Court its own abbreviated version of the allegations and the law. Moderna's conclusory motion to dismiss is not enough.

The Court should therefore deny this motion on two grounds. First, Northwestern plausibly alleged that Moderna directly infringed its patents under the "make" and "use" elements of Section 271(a), and Northwestern's claims reside comfortably within the boundaries drawn by the Federal Circuit. Second, Moderna's approach to Northwestern's position—bereft of any authorities or discussion of the actual issues—falls well short of the "full and fair opening brief" that the Delaware Local Rules require. D. Del. LR 7.1.3(c)(2). Because it failed to "squarely argue[]" this issue, Moderna has now forfeited its argument. *Jackson v. NuVasive, Inc.*, No. 21-cv-53-RGA, 2023 WL 6387866, at *2 n.1 (D. Del. Sept. 29, 2023) (citation omitted). Either way, the Court should deny the motion and allow Northwestern to prove its theories in discovery.

1. Moderna directly infringes the '155 patent by "delivering" an "oligonucleotide structure" that promotes uptake of its mRNA

Northwestern alleges that Moderna directly infringes the '155 patent, which claims a "method for promoting cellular uptake of an oligonucleotide," including the step of "delivering a oligonucleotide structure to a subject or a biological sample in an effective amount for promoting cellular uptake of the oligonucleotide in the subject or biological sample." D.I. 1-2, Ex. I ('155 patent) at claim 1. Moderna rests its opposition entirely on the unfounded assumption that only a physician can perform the steps of the '155 patent. D.I. 13 (Defs.' Br. in Supp. of Mot. to Dismiss) (hereinafter "Mot.") at 10. That ignores two grounds by which Northwestern alleges that Moderna performs the claimed steps of the '155 patent.

First, Northwestern alleges that Moderna directly infringes, because Moderna, not a physician, is responsible for "delivering" the mRNA into the cell. D.I. 1 at ¶ 127. As Merriam-Webster defines, "deliver" means "to send (something aimed or guided) to an intended target or

destination."[1] Northwestern alleged "the Accused Products *deliver* an oligonucleotide structure to a patient in an amount capable of promoting cellular uptake of an oligonucleotide in the patient." D.I. 1 at ¶ 127 (emphasis added). Moderna itself states that "lipid particles . . . enable *delivery* of the nucleoside-modified mRNA into host cells . . . ." *Id.* ¶ 95 (emphasis added) (citation omitted); *see also id.* ¶¶ 13, 30, 48, 61, 80. If Moderna contends that "delivering" is defined as something other than its ordinary and plain meaning, Moderna should make those arguments at claim construction, not now. This apparent difference illustrates that Northwestern's allegations are not ripe for dismissal.

The fact that a physician must administer the vaccine before Moderna may deliver the mRNA does not insulate it from direct infringement. For instance, the Federal Circuit held that a defendant could directly infringe a method patent even if one step of the patent implied action from a third party. *SiRF Tech., Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319, 1330-31 (Fed. Cir. 2010). Just as a patent for a method of making a phone call may imply the involvement of a party who routes the call through a network, a method of delivering an oligonucleotide could imply the involvement of an administering physician. *Id.* at 1330. Further, Moderna errs in relying on *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003). In that case, the patent-in-suit claimed a method for "treating" a patient, and the Federal Circuit held a manufacturer could not "treat" a patient as claimed. *Id.* at 1363. But "treating" language is absent from the '155 patent claims, and "delivering" is different from claim terms like "treating" or "injecting."

Second, Northwestern alternatively alleges a direct infringement claim through a theory of divided infringement. "[L]iability under § 271(a) can also be found when an alleged infringer

[1] *Deliver*, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/delivering (last visited Jan. 22, 2025).

conditions participation in an activity or receipt of a benefit upon performance of a step or steps of a patented method and establishes the manner or timing of that performance." *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1023 (Fed. Cir. 2015) (en banc) (per curiam). By this account, Moderna directly infringes because it is a physician who "deliver[s]" the oligonucleotide structure, but Moderna "directed or controlled" the physician's delivery of the structure. *Id.* at 1025. As Northwestern alleges, Moderna directs physicians to administer the Accused Products through intramuscular injection. D.I. 1 at ¶¶ 93, 127 (citing D.I. 1-3, Ex. U (Spikevax package insert (Apr. 2024))). The package insert, incorporated into the complaint, establishes the way the delivery must occur, directing the physician on vaccine preparations, dosage amount, and contraindications that the physician must consider. *See generally* D.I. 1-3, Ex. U (Spikevax package insert (Apr. 2024)). Moderna therefore conditions physician participation in administering the vaccine on how he or she goes about "delivering" the vaccine.

Northwestern pled two ways by which Moderna directly infringes the '155 patent. Because Moderna failed to show a deficiency in either, the Court should deny the motion.

2. Moderna directly infringes the '686 and '026 patents when it "makes" and "uses" the claimed apolipoprotein-binding nanoparticles

Northwestern alleges that Moderna directly infringes the '686 and '026 patents because Moderna "makes" and "uses" the claimed apolipoprotein-containing nanoparticles after administration—a practice that the inventors contemplated and described in the patent specifications. *See* '026 patent, 23:51-59;'686 patent, 15:9-16. In the scant five sentences it devotes to opposing these claims, Moderna does not cite or apply cases—it simply asks the Court to dismiss because Northwestern does "not allege apolipoprotein-containing complexes form when the vaccine is in Moderna's hands." Mot. at 11. Not only is that at odds with the complaint, this contrived standard lacks support in the law. The Court should deny this motion.

a) "Makes"

Moderna infringes under Section 271(a) by "making" the claimed technology when it configures its vaccines so that its nanoparticles bind *in vivo* to apolipoproteins and combine into infringing nanoparticles. *See* D.I. 1 at ¶¶ 105-19, 136, 150. The Federal Circuit defined "makes" broadly enough to extend liability to a party that does not itself direct the assembly, provided that the party "makes a combination . . . that is 'configured' to infringe." *Centrak, Inc. v. Sonitor Techs., Inc.*, 915 F.3d 1360, 1373 (Fed. Cir. 2019). To be liable for infringement under this term, a party does not need to manufacture each individual component: "assembling the components of an invention is an infringing act of making the invention." *Lifetime Indus., Inc. v. Trim-Lok, Inc.*, 869 F.3d 1372, 1378 (Fed. Cir. 2017); *see also Centrak*, 915 F.3d at 1372.

To configure its vaccines to form the infringing structure, Moderna selects a ratio of components for its vaccine that leads to a charge associated with the nanoparticles. D.I. 1 at ¶¶ 106-07, 137, 151. This selection "influences the degree to which the LNP binds to apolipoproteins present in the body." *Id.* ¶ 107. "[I]t is the specific ratio and selection of LNP components within Spikevax that cause the binding between the LNP and the apolipoprotein in the patient's body." *Id.* ¶ 114. "Moderna specifically intends and manufactures Spikevax to ensure that the LNP binds with apolipoproteins . . . ." *Id.* ¶ 112. The Asserted Patents describe how a party might make these decisions, teaching for instance that "the shell of the structure can be designed to include components with properties that allow favorable interaction (e.g., binding, adsorption, transport) with the one or more materials from the subject." *See, e.g.*, '026 patent, 16:34-38; '686 patent, 7:54-58. Notably, Moderna—not the patient, the physician, or any other third party—causes this combination to occur. *See* D.I. 1 at ¶ 112.

Moderna may disagree with these allegations, but its recourse is to disprove them during discovery, not ignore them in its motion to dismiss. Similarly, Moderna made a footnoted

argument about Northwestern's supposedly inconsistent use of the Sebastiani article. Mot. at 11 n.4. That is a fact dispute that the parties may litigate during discovery, summary judgment, or before the jury, not through Moderna's motion to dismiss. Northwestern plausibly alleged Moderna directly infringes because it makes the claimed nanoparticles.

b) "Uses"

Moderna "uses" the structures claimed in the '686 and '026 patents, because it designs its vaccines so that Moderna can put into service all of Northwestern's claimed technology, including the necessary apolipoproteins. *See* D.I. 1 at ¶¶ 93-115, 137, 151.

"[T]o 'use' a system for purposes of infringement, a party must put the invention into service, *i.e.*, control the system as a whole and obtain benefit from it." *Centillion Data Sys., LLC v. Qwest Commc'ns Int'l, Inc.*, 631 F.3d 1279, 1284 (Fed. Cir. 2011). "Use" is a "comprehensive term and embraces within its meaning the right to put into service any given invention." *NTP, Inc. v. Rsch. in Motion, Ltd.*, 418 F.3d 1282, 1316-17 (Fed. Cir. 2005) (quoting *Bauer & Cie v. O'Donnell*, 229 U.S. 1, 10-11 (1913). "[U]se does not require a party to 'exercise physical or direct control over each individual element of the system.'" *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1239 (Fed. Cir. 2017) (quoting *Centillion*, 631 F.3d at 1284).

Moderna "uses" the claimed technology, because it puts into service each element of Northwestern's claimed technology and benefits from the resulting delivery of its mRNA. Through the design of its Accused Products, Moderna puts into service each element of the claimed structures, including a core, lipid shell, and an apolipoprotein. D.I. 1 at ¶¶ 103-04, 106-07, 114-15. Moderna "design[s] the size, composition, and charge of the LNP so that it facilitates binding with apolipoprotein." *Id.* ¶¶ 137, 151. Moderna controls the system, as its design decisions "influence[] the degree to which the LNP binds to apolipoproteins present in the body." *Id.* ¶ 107. "[I]t is the specific ratio and selection of LNP components within Spikevax that

cause the binding between the LNP and the apolipoprotein in the patient's body." *Id.* ¶ 114. "Moderna specifically intends and manufactures Spikevax to ensure that the LNP binds with apolipoproteins . . . ." *Id.* ¶ 112. The Asserted Patents teach a party how to use the claimed structure in this fashion. *See, e.g.*, '026 patent, 16:34-38; '686 patent, 7:54-58. Moderna benefits from the claimed nanoparticle because its mRNA can thereby enter the cell and confer immunity to the patient. D.I. 1 at ¶ 109; *see also id.* ¶¶ 137, 151. As it recognizes, the nanoparticles "enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen." *Id.* ¶ 95 (quoting D.I. 1-3, Ex. U at 28 (Spikevax package insert (Apr. 2024))).

3. Moderna forfeited its direct infringement argument

In moving to dismiss these direct infringement claims, Moderna presented just two paragraphs without any law on direct infringement or citations to the bulk of Northwestern's relevant allegations. Mot. at 10-11. But the Delaware Local Rules do not allow a party to make generic, broadly stated arguments. D. Del. LR 7.1.3(c)(2). They require a "full and fair opening brief." *Id.* Because it failed to "squarely argue[]" this issue, Moderna forfeited its argument. *NuVasive*, 2023 WL 6387866, at *2 n.1 (citation omitted). To defend its claims from Moderna's drive-by attack, Northwestern had to develop the issues and law for the first time in its response brief. Now, Moderna can poke and prod at these positions without Northwestern ever getting a fair opportunity to reply—exactly what the Delaware Local Rules prohibit. *See* D. Del. LR 7.1.3(c)(2) (moving party "shall not reserve material for the reply brief"); *In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, No. 20-md-2930-RGA, 2024 WL 4723274, at *4 (D. Del. Nov. 8, 2024) ("Arguments first made in reply briefs are forfeited."). For this reason, the Court should find that Moderna forfeited its motion to dismiss the direct infringement claims. And if the Court decides Moderna did not forfeit these arguments, Moderna cannot develop a new motion to dismiss position in its reply.

4. Moderna directly infringes the Asserted Patents when it commercially tests the Accused Products

Northwestern plausibly alleged that Moderna infringes the Asserted Patents because it "uses" the claimed technology through its testing of the Accused Products. D.I. 1 at ¶¶ 124, 138, 152. Moderna does not dispute it would directly infringe through testing. Mot. at 11. Rather, Moderna contends that its conduct falls within the Section 271(e)(1) safe harbor, which exempts from infringement any testing that is "reasonably related" to federal regulatory approvals. *Id*.

Moderna is mistaken for two reasons. First, Section 271(e)(1) is an affirmative defense that Moderna cannot assert through a 12(b)(6) motion. *REGENXBIO Inc. v. Sarepta Therapeutics, Inc.*, No. 20-cv-1226-RGA, 2022 WL 609141, at *2 (D. Del. Jan. 4, 2022); *see also Amgen, Inc. v. F. Hoffman-LaRoche Ltd.*, 456 F. Supp. 2d 267, 273 (D. Mass. 2006) (collecting cases recognizing Section 271(e)(1) as an affirmative defense). "[T]he Federal Rules of Civil Procedure require a defendant to plead an affirmative defense, like a statute of limitations defense, in the answer, not in a motion to dismiss." *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (reversing order granting a motion to dismiss based on affirmative defense).

Second, a motion to dismiss is particularly inappropriate when the complaint presents factual disputes over whether testing included "commercial activities outside the scope of the safe harbor." *REGENXBIO Inc. v. Sarepta Therapeutics, Inc.*, No. 20-cv-1226-RGA, 2022 WL 1624703, at *1 (D. Del. May 23, 2022). The complaint makes clear that Moderna's accused testing was not limited to the federal regulatory process. Northwestern alleges "*in vivo* testing during clinical trials," which encompasses commercial activity that would fall outside of Section 271(e). *See* D.I. 1 at ¶¶ 124, 138, 152. Northwestern's complaint includes exhibits with further detail on the scope of Moderna's commercial testing, which falls outside the scope of Section 271(e). Moderna engages in product-improvement testing that "allowed us to make significant

improvements in the potency of our LNPs." D.I. 1-1, Ex. A at 18 (Moderna, Inc. Annual Report Form 10-K (Feb. 27, 2020)). Further, Moderna "conduct[s] research to identify novel mRNA technology improvements, including identifying novel methods of mRNA delivery, such as LNPs that improve distribution and uptake of mRNA to specific tissues." *Id*. at 163. These are commercial advances, not regulatory requirements, and they would all fall outside Section 271(e). Although Northwestern does recognize in the '686 and '026 patent allegations that some testing goes to FDA approval, a plaintiff does not need to "plead around an affirmative defense in his complaint, which is inconsistent with Rules 8 and 12(b)(6)." *Schmidt*, 770 F.3d at 252.

* * *

Moderna chose a slapdash approach to opposing the direct infringement claims, which should result in forfeiture of these arguments. Even if not, Northwestern plausibly alleged how Moderna directly infringed the '155 patent by "delivering" its mRNA to patients. Northwestern also plausibly alleged how Moderna infringes the '026 and '686 patents when it "makes" and "uses" the claimed structures. And Northwestern alleged commercial testing that directly infringes all three patents. The Court should allow these claims to proceed.

B. The complaint sufficiently alleges that Moderna indirectly infringed the Asserted Patents

Moderna makes two unsuccessful arguments to dismiss Northwestern's indirect infringement claims.[2] First, Moderna says that it lacked pre-suit knowledge necessary for claims under Section 271(b), 271(c), and 271(f). Mot. at 12, 14, 16. Second, Moderna claims that Northwestern failed to allege its Section 271(c) and 271(f) claims because it did not specifically allege how its products were specially adapted to infringe. Mot. at 14, 16. Both fail.

[2] Northwestern does not dispute Moderna's position that Section 271(f) does not extend to the method claims of the '155 patent. *See* Mot. at 16.

1. Northwestern adequately alleges pre-suit knowledge necessary for indirect infringement, while Moderna misstates the law relating to this element

Northwestern alleges that, prior to this litigation, Moderna knew about its infringement of the Asserted Patents. *See* D.I. 1 at ¶¶ 14, 82-84, 105-15, 125-29, 139-43, 153-57. As the complaint lays out, Moderna received an October 2023 notice letter that establishes this knowledge. *Id.* ¶¶ 129, 143, 157. Further, Moderna was aware prior to the letter, given Moderna's stated need for a lipid nanoparticle technology, the prominence of the Northwestern inventors in that field, and Moderna's frequent citations to their work. *Id.* ¶¶ 48, 50-53, 82-84. Moderna nevertheless moves to dismiss.

Moderna says that the letter is insufficient because it "does not allege that Moderna infringed any particular patent, let alone explain the basis for any infringement allegations." Mot. at 13. In addition to a failure to reliably report the content of the letter, Moderna is apparently unaware of clear requirements about what the plaintiff must allege to establish knowledge based on such a letter: "There is no requirement that a plaintiff pleads notice of how specific product features infringe specific patents." *Bench Walk Lighting*, 2022 WL 606287, at *2. Rather, to establish knowledge needed for induced infringement, a plaintiff need only plead a notice letter that identifies (1) the asserted patents, (2) the accused products, and (3) the plaintiff's view that the defendant infringed. *See, e.g.*, *AlexSam, Inc. v. Aetna, Inc.*, 119 F.4th 27, 46 (Fed. Cir. 2024); *Lifetime Indus.*, 869 F.3d at 1379-80. Moderna relies on dicta from *Commil* that has nothing to do with the standard for pleading an indirect infringement claim. *See generally Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632 (2015) (appeal from jury verdict).

Moderna showcases Northwestern's letter in its motion to dismiss presumably in an attempt to identify deficiencies, but the letter demonstrates that Northwestern (1) identifies the Asserted Patents, (2) describes the accused technology at issue, (3) notifies Moderna of

Northwestern's belief that Moderna practices the claimed technology, and (4) proposes a license. D.I. 14-1, Moderna Ex. 1 (Northwestern letter to Moderna (Oct. 13, 2023)). This Court has repeatedly denied similar motions to dismiss based on notice letters with comparable or even less disclosure, such as:

- A letter that merely notified the defendant of the asserted patents. *Metrom Rail, LLC v. Siemens Mobility, Inc.*, No. 22-cv-49-RGA, 2023 WL 2598775, at *1 (D. Del. Mar. 22, 2023)
- A notice identifying the asserted patents, accused systems, notice of infringement, and an offer to license. *Jackson v. SeaSpine Holdings Corp.*, No. 20-cv-1784-RGA, 2022 WL 610703, at *4-5 (D. Del. Feb. 14, 2022); and
- A letter alerting defendant to multiple patents and accused products that practiced the patents. *Bench Walk Lighting*, 2022 WL 606287, at *2.

Moderna received *more* notice than the alleged notifications in *Metrom Rail*, *SeaSpine Holdings*, or *Bench Walk*. Northwestern plausibly alleged pre-suit knowledge of indirect infringement.

Moderna fares no better arguing that Northwestern failed to allege pre-suit knowledge arising from Moderna's citations to the inventors' work, a separate ground that supports Northwestern's indirect infringement claims. "At the pleading stage, alleged knowledge of patent family members and related patents, along with other allegations, can be sufficient to overcome a motion to dismiss." *Novozymes N. Am., Inc. v. Danisco US Inc.*, No. 19-cv-01902-JDW, 2020 WL 12895027, at *3 (D. Del. Feb. 12, 2020). Northwestern's allegations give rise to the reasonable inference that Moderna knew about the inventors' work, the Asserted Patents, and the infringement that Northwestern now raises.

As Northwestern states, its inventors were among the most prominent researchers in their field, working at a world-renowned research institution. D.I. 1 at ¶¶ 50-53. In contrast, Moderna was, in its own words, "too underfunded and small to create its own delivery system" for its mRNA. *Id.* ¶ 48 (citation omitted). As the Northwestern inventors received acclaim for their

breakthroughs, they also disclosed their findings in patents. *Id.* ¶ 63. Moderna cited to these family member patents in several of its own patents, including three patents that cover Spikevax and at least eight other patents. *Id.* ¶¶ 82-84. One Northwestern inventor, Dr. Chad Mirkin, was later recognized alongside Moderna co-founder Dr. Robert Langer for their common work in "nanostructured synthetic materials with biologically active molecules." *Id.* ¶ 51 (quoting D.I. 1-2, Ex. H (2024 Kavali Prize in Nanoscience)). From these allegations, the Court may reasonably infer that Moderna knew about Northwestern's claimed nanoparticles, needed the technology, and knew that its use infringed the Asserted Patents.

Finally, Moderna proposes that Northwestern's pre-suit knowledge allegations somehow depend on Moderna's package inserts. *See* Mot. at 14 & n.6. That is incorrect. As discussed above, Northwestern adequately alleges pre-suit knowledge based on (1) the notice letter and (2) the family member patent citations, when taken together with the other allegations in the complaint.

Moderna cannot escape Northwestern's indirect infringement claims by offering the Court its own version of the law and the allegations. With the proper standard and relevant allegations in hand, the Court should deny Moderna's motion.

2. Moderna ignores Northwestern's straightforward allegations that there are no substantially non-infringing uses of the Accused Products

Moderna also moves to dismiss Northwestern's Section 271(c) and 271(f) claims, arguing that Northwestern did not allege how the Accused Products are "specially made" to infringe or have no "substantial non-infringing use." Mot. at 15 (quoting D.I. 1 at ¶¶ 126, 140, 154). In particular, Moderna says that Northwestern never specifically alleges how its products are specially adapted to (1) bind apolipoproteins, (2) regulate gene expression, or (3) sequester cholesterol. *Id.* However, Northwestern pled just that. *See* D.I. 1 at ¶¶ 126, 140, 154. The

"affirmative pleading of the absence of substantial non-infringing uses renders the claim plausible." *Express Mobile, Inc. v. Squarespace, Inc.*, No. 20-cv-1163-RGA, 2021 WL 3772040, at *5 (D. Del. Aug. 25, 2021) (citation omitted). And Northwestern pled even more "facts that allow an inference that the components sold or offered for sale have no substantial non-infringing uses." *In re Bill of Lading*, 681 F.3d at 1337.

First, as to the binding apolipoprotein limitation, Moderna defies credulity to say Northwestern failed to allege how the Accused Products are "specially made" to bind apolipoproteins. These allegations pervade the complaint. *See, e.g.*, D.I. 1 at ¶¶ 105-15, 140-142, 154-156. As to the second limitation, Northwestern plainly alleged that Moderna's products are "specially made" to regulate gene expression. The complaint describes how the oligonucleotide regulates the expression of genes into proteins—like the SARS-CoV-2 S antigen or the preF protein antigen. *Id.* ¶¶ 95-97, 127, 141. Third, Northwestern likewise alleged how Moderna's products are specially adapted to sequester cholesterol. When the Accused Products bind to an apolipoprotein, the binding "increases the amount of cholesterol on the surface of the LNP." *Id.* ¶¶ 101, 127. Further, Northwestern's allegations allow the Court to reasonably infer that there is no use that avoids infringement: because Moderna designed its products to practice each element, a third party cannot employ them in a substantially non-infringing use. *Id.* ¶¶ 97, 101, 105-15, 126, 140, 154. Because Northwestern thoroughly pled the "no substantial non-infringing use" element, its Section 271(c) and (f) claims should stand.

* * *

The Court should deny Moderna's effort to dismiss Northwestern's indirect infringement claims. As to the knowledge element, Northwestern plausibly alleged pre-suit knowledge of infringement on two different grounds. As to the specially adapted element for the 271(c) and

271(f) claims, Northwestern provided specific allegations describing why the Accused Products infringe. The Court should deny Moderna's motion.

C. Northwestern plausibly alleges that Moderna willfully infringed after learning of the Asserted Patents prior to the litigation

Moderna rests its indirect infringement arguments on a misstatement of the law, and it compounds that error by attempting to dismiss Northwestern's willful infringement claims on similar grounds. Mot. at 17. Moderna says that Northwestern has failed to plead pre-suit knowledge of any infringement, so the willfulness claim must only rest on post-suit knowledge. That is wrong, for the reasons identified above. *See infra* § IV.B.1.

When a plaintiff alleges "pre-suit knowledge of the existence of the [asserted] patent," then it may plausibly allege a claim of willfulness infringement based on "pre-suit knowledge of the existence of the [asserted] patent." *LiTL LLC v. Lenovo (U.S.), Inc.*, No. 20-cv-689-RGA, 2022 WL 610739, at *10 (D. Del. Jan. 21, 2022); *see also Metrom Rail*, 2023 WL 2598775, at *1; *SeaSpine Holdings*, 2022 WL 610703, at *7; *Bench Walk*, 2022 WL 606287, at *2. Northwestern alleged that Moderna knew about the Asserted Patents. D.I. 1 at ¶¶ 82-84, 129, 143, 157. Because that is enough to plead willfulness, the Court should deny this motion.

D. The complaint alleges more than enough to notify Moderna how the Accused Products satisfy the "physisorbed" limitations of the '155 and '026 patents

Moderna contends that Northwestern did not plausibly allege that the Accused Products infringe two claims that require its oligonucleotides to "physisorb" to the structure. Mot. at 17-18. Moderna's argument is at odds with the rule that "[a] plaintiff is not required to plead infringement on an element-by-element basis." *Bot M8*, 4 F.4th at 1352. Rather, Northwestern must only plead enough so Moderna is notified which activity "is being accused of infringement." *Id.* (quoting *Lifetime Indus.*, 869 F.3d at 1379). Northwestern clearly met the pleading standard, and the Court should therefore deny Moderna's motion.

And even if the Court agreed with Moderna's unsupported suggestion of a heightened pleading standard, Northwestern would still clear that threshold:

Claim Limitation	Relevant Allegations
'155 patent, claim 2: "[T]he structure comprising . . . an oligonucleotide adapted to regulate gene expression associated with at least a portion of the shell, . . . wherein the oligonucleotide is *electrostatically physiosorbed* to a surface of the shell." (emphasis added)	D.I. 1 at ¶ 127: Moderna's "oligonucleotide is also associated with at least a portion of the lipid shell through *electrostatic physisorption*, given the difference in charges between the oligonucleotide and the lipids comprising the shell." (emphasis added)
'026 patent, claim 1: "A nanostructure comprising an oligonucleotides adapted to regulate gene expression *physisorbed* to the surface of a synthetic carrier . . . ." (emphasis added)	D.I. 1 at ¶ 141: Moderna's "oligonucleotide is *physisorbed* to the surface of the synthetic LNP due to the difference in charge between the lipids comprising the shell and the oligonucleotide itself." (emphasis added)

Elsewhere in the complaint, Northwestern provides more detail on why physisorption occurs between the oligonucleotide and the shell surface: mRNA is the oligonucleotide, and it has a negative charge. D.I. 1 at ¶ 97. The shell lipids includes SM-102, which is a positively charged lipid. *Id.* ¶¶ 98-99. SM-102 "associate[s] with negatively charged mRNA during particle formation." *Id.* ¶ 99; *see also id.* ¶ 106. Northwestern's allegations on this issue well exceed the short and plain statement of facts required for a plausible complaint.

Moderna cannot credibly claim that Northwestern fails to allege these elements. Moderna points to an allegation in paragraph 106 of the complaint that lists physisorption as one of several relationships that form between the mRNA and the lipids, and they say that the use of "and/or" in that paragraph means that Northwestern failed to allege that physisorption actually occurs. Mot. at 18. As to paragraph 106 itself, that is not a very compelling argument. And when viewed against the entire complaint—with its additional allegations describing how Moderna infringes these limitations—the argument fails. "Allegations of direct infringement do not require much."

Metrom Rail, 2023 WL 2598775, at *1 n.2. Northwestern's pleadings provide more than enough to satisfy its obligations under Rule 8.

E. Moderna's confusing and premature Section 101 arguments do not invalidate the '686 patent

Moderna asks the Court to invalidate the '686 patent as a natural phenomenon, but it does not tell the Court which natural phenomenon should invalidate the patent, even though comparing the patent with the natural phenomenon is the very first step of any inquiry under *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014). Mot. at 18-20. Should the '686 patent be compared to the magnetic bacteria of Matsunaga, the reference before the examiner? The intracellular particles formed by the bacteria? The apolipoprotein? Moderna will not say. This tight-lipped approach does not even reach the threshold for stating an argument under *Alice*. Two other deficiencies confirm that the Court should reject this Section 101 argument.

First, contrary to Moderna's suggestion, the file history supports—not weakens—the patent eligibility of the '686 patent. During prosecution, Northwestern argued that the '686 patent was eligible under Section 101. Moderna itself concedes that the examiner considered the patent eligibility of the current version of claim 1, which claims a structure including an apolipoprotein. Mot. at 20. The examiner's conclusion: "the compositions are not naturally occurring." D.I. 14-1, Moderna Ex. 3 at 50 ('686 file history excerpts).

Moderna tries to sneak past this conclusion by pointing to earlier exchanges in the file history, but these also bolster the patent's eligibility. In a March 2012 correspondence, the examiner considered intracellular particles (lacking an apolipoprotein) formed by magnetic bacteria. *Id.* at 4. The examiner held that a prior version of claim 1, which lacked an apolipoprotein, was ineligible given these particles. *Id.* at 4-5. Yet, at the same time, the examiner did not find that dependent claim 111 (which included the apolipoprotein limitation)

was patent ineligible. *Id.* When Northwestern added an apolipoprotein limitation to claim 1, the examiner found that the claimed invention was now patent eligible under Section 101. *Id.* at 50. Nothing in these exchanges turned on whether the apolipoprotein itself was "a natural phenomenon," as Moderna confusingly contends in its motion. *Id.*

Second, this argument is poorly suited for resolution on a Rule 12(b)(6) motion. Without the benefit of claim construction or discovery, Moderna invites the Court into a highly fact-dependent inquiry regarding patent eligibility. But, at this stage, a Section 101 analysis is appropriate "only when there are no factual allegations that, taken as true, prevent resolving the eligibility question as a matter of law." *TakaDu Ltd. v. Innovyze, Inc.*, No. 21-cv-291-RGA, 2022 WL 684409, at *3 (D. Del. Mar. 8, 2022) (quoting *Aatrix Software, Inc. v. Green Shades Software, Inc*., 882 F.3d 1121, 1125 (Fed. Cir. 2018)). To prevail on its Section 101 argument, Moderna faces a "significant burden." *Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 527 (D. Del. 2014) (such dismissals are "rare"). Moderna's attempt here falls well short.

V. CONCLUSION

For the foregoing reasons, the Court should deny Moderna's Motion to Dismiss.

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Dated: January 23, 2025

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